CareStart™ COVID-19 Antigen

A Rapid POC Test

FDA Authorized

Under EUA

CE

Due to the highly contagious nature and global health crisis, SARS-CoV-2 has been designated as a pandemic by the World Health Organization (WHO) and continues to have devastating impacts on healthcare systems and the world economy including the U.S. To effectively end the SARS-CoV-2 pandemic, systematic screening and detection of both clinical and asymptomatic COVID-19 cases is critical.

As an intended point-of-care (POC) designated test with a 10 minute processing time, CareStart™ COVID-19 Antigen Test allows effective screening of COVID-19 infection on a large scale

Features	Features Clinical
– Lateral flow assay – Rapid results in 10 minutes – Minimally invasive specimen collection (nasopharyngeal) – Intended at POC setting (i.e., in patient care settings) by medical professionals	– Detect SARS-CoV-2 nucleocapsid protein antigen – Identify acute infection with high sensitivity and 100% specificity

The CareStartTM COVID-19 Antigen test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories and at the Point of Care by medical professionals. This test has been authorized only to detect the presence of the SARS-CoV-2 nucleocapsid protein antigen,, not for any other viruses or pathogens; this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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COVID-19 Rapid POC Antigen Test, Box of 20

Phoenixpro health has available for immediate shipment the CareStart COVID-19 Antigen Rapid Point of Care test kits. Get results in ten minutes. For use by healthcare professionals in point-of-care settings. Very affordable. No separate analyzer equipment needed. Authorized by the FDA for emergency use.

Provide an important service to your patients, essential workers, government agencies, educators pharmacy and others who need information relating to their exposure to or infection of COVID-19.

With the second wave of COVID-19 infections underway, the demand for testing solutions has never been higher. TheCareStart test test kit from Phoenixpro Health can be an important part of providing this service to your community.

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COVID-19 ANTIGEN RAPID TESTS

Test	Carestart Antigen
Technique	Lateral flow chromatographic Immunoassa
Instrument	No
Preparation 11me	None
Known Cross Reactivity	No
Processing time	1Ominutes
Clinical Sensitivity	90%
Clinical Specificity	100%
Specimen Type	Nasopharygeal and Nasal swabs
Analytical Sensitivity (LOO)	8x10² TCIDso/mL[a]
Point-of-Care	Yes
Target	Nucleocapsid antigen
FDA Authorization	**YES**

a*-This LOO is when the swab was used with VTM and not CareStart extraction buffer. With CareStart extraction buffer LOO is 1.2X *10^2 TC/D50/mL*

For Emergency Use Authorization (EUA) Only

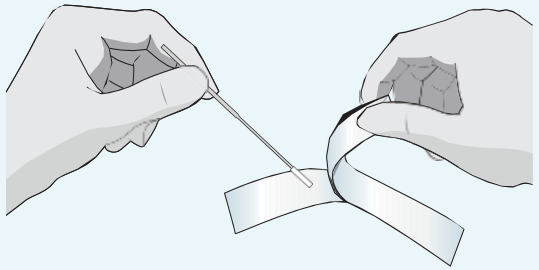
The *CareStart*™ COVID-19 Antigen test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within ve days of symptom onset.

Only Rx IVD 1°C 30°C

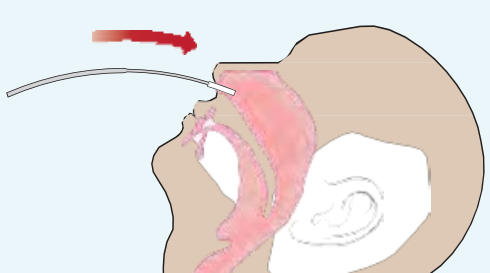
IMPORTANT

-Refer to the Package Insert for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
-Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information.
-Biotin Interference: False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (> 10 mg per day). Biotin levels of 2.5 µg/mL have been demonstrated to result in false negative test results.
-The extracted sample must be used within 4 hours of preparation when stored at room temperature.
-Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

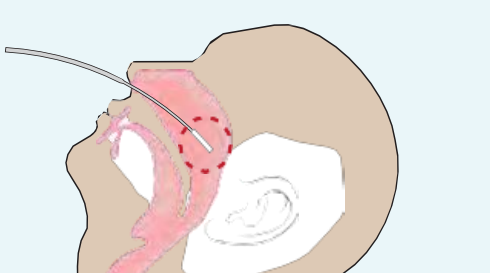
SPECIMEN COLLECTION AND HANDLING



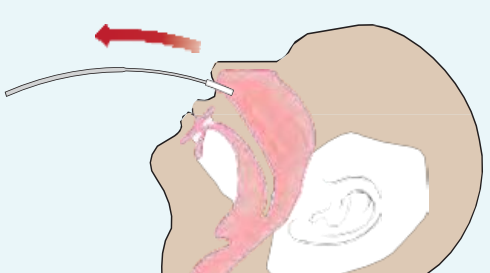
Remove from the pouch a nasopharyngeal swab



Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.



Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.



Slowly remove the swab from the nostril while rotating it.

FACT SHEET FOR HEALTHCARE PROVIDERS

October 23, 2020

***CareStart*™ COVID-19 Antigen**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the *CareStart*™ COVID-19 Antigen test.

The *CareStart*™ COVID-19 Antigen test is authorized for use using nasopharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Access Bio, Inc. – CareStart™ COVID-19 Antigen.

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

This test is to be performed only using nasopharyngeal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

- The *CareStart*™ COVID-19 Antigen test can be used to test nasopharyngeal swab specimens directly collected or collected in BD universal transport media.
- The CareStart™ COVID-19 Antigen test should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider and who are within the first five days of onset of symptoms.
- The *CareStart*™ COVID-19 Antigen test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests.
- The *CareStart*™ COVID-19 Antigen test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (*see links provided in "*Where can I go for updates and more information?*" section).

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The *CareStart*™ COVID-19 Antigen test has been designed to minimize the likelihood of false positive test results. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 antigens were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via the *CareStart*™ COVID-19 Antigen test.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in "Where can I go for updates and more information" section).

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved

or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html
Discontinuation of Isolation:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html
Influenza: https://www.cdc.gov/flu/index.htm

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

October 8, 2020

San Joon Han
Associate Principal Scientist / R&D Division
Access Bio, Inc.
65 Clyde Road Suite A
Somerset, NJ 08873

Device:	*CareStart* COVID-19 Antigen test
Company:	Access Bio, Inc.
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens directly collected, or collected in BD universal transport media, from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear San Joon Han:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Access Bio, Inc..
[2] For ease of reference, this letter will use the term "your product" to refer to the *CareStart* COVID-19 Antigen test used for the indication identified above.

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MEDLINK WORLD LLC Order Form

CareStart - COVID-19 Antigen RAPID TEST

1 Box = 20 tests/box

Minimum Order Quantity = 500 Tests **(First test order volume could be as low as 100 tests)**

PRODUCT	QUANTITY	HCP PRICE	TOTAL
Rapid Antigen Test Kit			$
		Subtotal	
		Shipping	
		Credit Card Processing Fee (3.75%)	
		Total	

Shipping Information: Buyer responsible for shipping costs. Totalled and billed at 1.5% of total selling price.

Organization Name

Contact Name

Mailing Address

City | State | Zip Code

Email | Phone

147 W, 35th St, New York, NY, 10001
P: 718-428-2560 | F: 678-868-4807
info@medlinkworld.com

Payment Information:

Use Payment Information on File? ◯ Yes ◯ No If not using payment information on file, please provide payment details below

Credit Card payments only available for orders under $5,000. Direct Wire Transfer is preferred method of payment and wiring instructions will be also provided on invoice to the Buyer. ACH Payment available on orders up to $10,000 USD. Certified Check payment also available but order will not ship until payment is received.

Credit Card: +3.75% Courtesy fee for credit card transactions. No fee for wire.

Name on Card

Credit Card Number | Expiration Date

Billing Address (if different from shipping address) | Security Code

City | State | Zip Code

Wire:

Bank Name | Citbank N.A | Account Number | 6863970886

Account Name | Medlink World, LLC | Routing Number | 021000089

Account Address | 176-50, Union Tpke, Jamaica, NY 11366

Terms for order forms & Invoices – Direct payment

Billing and Payment Terms: Customer will be charged in full upon signing of order form. Payments are due upon receipt of order form unless otherwise agreed upon between both parties. Signature on this order form constitutes agreement with the product and materials order above. 100% will be billed and must be paid in full prior to product being shipped or hand delivered. Final shipment info with tracking number will be provided upon full payment of your order. Direct wire transfer, certified check, credit card and ACH payment options available based on billing amount

Product: This test has received an Emergency Use Authorization from the Federal Drug Administration (FDA). The CareStart™ COVID-19 Antigen Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare providers.

Auto-ship Program: Subject to the commercial availability of Antigen Testing, Purchaser will commit to Diagnostic COVID Rapid Testing solely from Medlink World LLC and its affiliates for a period of at least 6 months. Seller agrees to offer the Purchaser a 10% discount on COVID Rapid Tests when purchased each month from the execution of the Order Form. Discount will begin on the 2nd month of re-ordering. By signing below, I acknowledge that I/we fully understand and will abide by the above. I/we further agree to pay the total due indicated above via credit card or wire transfer for the above agreed upon products. I/we understand products will not be shipped until total due is paid-in-full.

Date:_____ Signature: _____

UNITED STATES CUSTOMERS: EMERGENCY USE TEST PURCHASE ACKNOWLEDGEMENT

This Emergency Use Test Purchase Acknowledgement ("Agreement") is entered into by and between the Company (also "Supplier") and the Client ("Purchaser") and is effective as of date set forth next to the Buyer's signature.

The Purchaser agrees that the tests purchased by Purchaser from the Company ("Tests") are for emergency use authorized (EUA) test purposes only and have been approved and licensed for sale or use in the U.S. by the U.S. Food and Drug Administration ("FDA") under specific EUA guidance. The Tests are provided by Company to Purchaser pursuant to the Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency as revised on the web on May 11, 2020 (or as per most recent) by U.S. Food and Drug Administration ("The Policy"), which may be found here: https://www.fda.gov/media/135659/download

as well as specific information, instructions and evaluation data pertinent to "Tests" use as provided in the "authorized serology test performance" section of the FDA website, ("Serology Section"), available here:

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance

All uses of the tests by the Purchaser shall be consistent with the Policy and Serology Section. Purchaser shall comply with the Policy guidance including, but not limited to, validation, FDA notification, reporting of results, Emergency Use Authorization ("EUA"), clinical testing, claims, restrictions and indications for use and distribution. Collection and interpretation of the Tests shall only be performed by accredited medical professionals. The Tests shall not be made available, sold, distributed or marketed, directly or indirectly, to the general public or outside of their indication for use.

The Purchaser shall not alter, modify, remove or deface the labelling on the Tests.

CE COUNTRIES: SELF DECLARE CE MARK AND TUV AUDIT/LISTING

The Purchaser agrees that the tests purchased by Purchaser from the Company ("Tests") meet the quality certification level of "CE Mark", which is a self-declared process, and a certificate has been granted to the Manufacturer. Seller will provide CE certificate, and any other necessary paperwork,

FURTHER ACKNOWLEDGEMENT – ALL POTENTIAL PURCHASERS IN ALL REGIONS

THE TESTS SHALL ONLY BE USED FOR PRELIMINARY SCREENING PURPOSES AND SHALL ONLY BE USED TO DETERMINE IF ADDITIONAL TESTING IS REQUIRED, AND AS DICTATED BY END MARKET REGULATIONS.

The Purchaser shall not alter, modify, remove or deface the labelling on the Tests.

The Purchaser agrees to indemnify, defend and hold harmless Company and its officers, directors, shareholders, employees, agents, representatives, successors and assigns from any and all claims, demands, losses, liabilities, judgments, awards and costs (including attorney's) fees arising out of or relating to the breach of this Agreement by the Purchaser or any person affiliated with the Purchaser.

I/We, are authorized to sign this agreement on behalf of the Purchaser and the information given is true and correct and acknowledge the terms and conditions as stated above and agree to abide by these terms.

PURCHASER:_____ TITLE:_____

NAME: _____ DATE: _____

SIGNED: _____